

REMARKS

The applicants appreciate the Examiner's thorough examination of the application and requests reexamination and reconsideration of the application in view of the following remarks.

The applicants appreciate the Examiner's indication that claims 16-18 are allowed.

The Examiner rejects claims 1-5 and 10-13 under 35 USC §102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0045848 to *Jaafar et al.*

Independent claim 1 of the subject patent application is directed to an endovascular tissue removal device comprising a lumen including a distal steerable tip portion extending from a joint portion, registration means for holding the joint portion fixed in place in the vasculature, and a source of ablation energy in communication with the lumen whereby tissue can be resected by ablation energy as the tip portion is steered within the vasculature. Independent claim 11 also includes the feature of a lumen including a distal steerable tip portion extending from a joint portion.

Jaafar is directed to an apparatus and method for treatment of cerebral aneurysms, arterial-vascular malformations and arterial fistulas. The Examiner asserts that *Jaafar* discloses "a device comprising a lumen (16) including a steerable tip portion (36) extending from a joint portion (i.e. distal end of sheath 16 after the balloon). A registration means (balloon-21) holds the joint portion in place and a source of ablative energy (laser - 12) is in communication with the lumen and delivered to the tip portion via an optical fiber (32)".

However, *Jaafar* fails to disclose a distal steerable tip portion extending from a joint portion as claimed by the applicants. The steerable tip portion of the applicants' claimed invention is clearly shown in Figs. 4 and 5 of the subject application at reference number 102.

Upon delivery of the lumen to the desired location, a physician would steer tip portion 102 as shown at 106 and 108 to resect the tissue using laser energy.

Jaafar only discloses advancing an optical fiber into an aneurysm and irradiating the aneurysm. *Jaafar* fails to disclose, teach or suggest that the device includes a steerable tip portion as claimed by the applicants.

Accordingly, as *Jaafar* fails to disclose a steerable tip portion as claimed by the applicants, independent claims 1 and 11, and dependent claims 2-5 are patentable over *Jaafar*.

Independent claims 12 and 13 also include the feature that the tissue removal device includes a deflectable tip. *Jaafar* fails to disclose, teach or suggest in any manner that the optical tip is deflectable. Accordingly, independent claims 12 and 13 are patentable over *Jaafar* for at least this reason.

The Examiner also rejects claims 1-15 under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,366,490 to *Edwards*.

Edwards is directed to a medical probe device and method. The Examiner asserts that *Edwards* discloses “a lumen (14) having a steerable distal tip (i.e., stylet - 36) extending from a joint portion (34). A registration means, including balloons (30,32) hold the joint member in place during movement/treatment with the tip member. The tip member may include various devices, including RF electrodes and laser fiber optics (col. 5, lines 21-24) and is connected to an ablative laser source (see Abstract). The second balloon (30) is deemed to act in concert with the first balloon as a barrier (i.e. tissue is trapped between the two balloons)”.

However, as with *Jaafar*, *Edwards* also fails to disclose a distal steerable tip portion extending from a joint portion as claimed by the applicants. *Edwards* only discloses stylets 36

which can be extended until they penetrate a target tissue, not a steerable tip portion as claimed by the applicants.

Accordingly, as *Edwards* fails to disclose a steerable tip portion as claimed by the applicants, independent claims 1 and 11, and dependent claims 2-10 are patentable over *Edwards*.

Independent claims 12, 13 and 15 also include the feature that the tissue removal device includes a deflectable tip. *Edwards* fails to disclose, teach or suggest in any manner that the optical tip is deflectable. Accordingly, independent claims 12, 13 and 15, and dependent claim 14 are patentable over *Edwards* for at least this reason.

Additionally, claim 15 also includes the feature of a balloon inflatable on the ventricular side of the valve for supporting the leaflets of the valve.

Lower balloon 200 is disposable on the ventricular side of the heart valve under leaflets 204 and 206. Balloon 200 is connected to an inflation conduit which extends within multi-lumen catheter 100. An outer suction conduit may include a port for withdrawing tissue. Balloon 200 performs several important functions. First, it supports leaflets 204 and 206 of the valve as they are pushed closed by the tissue removal device before cutting for more accurate cutting. Balloon 200 with laser energy absorption or reflection layer 212 also prevents inadvertent cutting of any portion of mitral valve 216. See Fig. 5 of the subject application reproduced below.

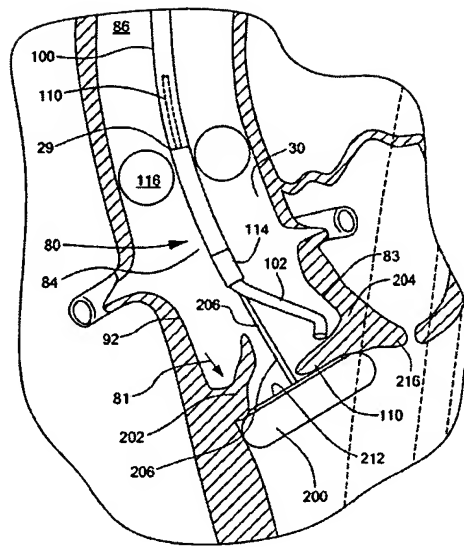


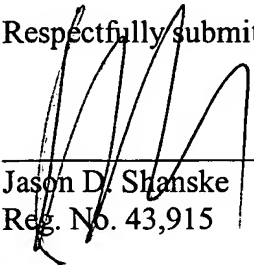
FIG. 5

The Examiner refers to annular balloon 30 of *Edwards* as an equivalent to the applicants' claimed balloon inflatable on the ventricular side of the valve. However, any resecting performed by the device of *Edwards* is accomplished by the stylets 36 of *Edwards*. Accordingly, a balloon as claimed by the applicants would have to be disposed ahead of stylet 36 to support the tissue being resected. *Edwards* fails to disclose, teach or suggest a balloon for supporting the tissue being resected as claimed by the applicants. Balloon 30 of *Edwards*' sole purpose is to stabilize the catheter and dilate the urethral lumen.

Edwards fails to disclose a balloon inflatable on the ventricular side of a valve to support the leaflets of the valve as claimed by the applicants. Accordingly, independent claim 15 is patentable over *Edwards* for at least this additional reason.

If for any reason this Preliminary Amendment is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the undersigned or his associates, collect in Waltham, Massachusetts, (781) 890-5678.

Respectfully submitted,



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